

#### **4.0 Service to the Client and Review of Contract, Tenders, and Work Request**

##### **4.1 Service to the Client**

4.1.1 As necessary, the laboratory works with the client to clarify test requests, device operation and test results. The client is provided controlled access to the laboratory to observe type evaluations of the device. To ensure confidentiality, information and devices of other clients are not visible during a client visit to the laboratory. The laboratory communicates with the client at any time prior to, during and after the type evaluation as needed to address any questions, changes and test results. The laboratory provides the client with a summary and conclusion of the test results. The laboratory may receive feedback from the client that might improve the laboratory quality system. As appropriate client feedback will be reviewed by the quality manager and used to improve the quality system (see Appendix H, AP No. 6).

##### **4.2 Review of Contract, Tenders, and Work Request (Application)**

4.2.1 Contracts, tenders, and work requests received by the laboratory are in the form of type evaluation applications. Applications are received by the type evaluation manager as a request for testing. Typically the type evaluation manager reviews the application, and in many cases the review involves an evaluation of the laboratory workload and other essential factors before the device is assigned to the laboratory. Procedures are maintained for the review of type evaluation applications that lead to an agreement for testing (see Appendix H, AP No. 21). The procedures ensure that:

4.2.1.1 The requirements and test used are defined and understood

4.2.1.2 The laboratory is capable of meeting the requirements and has the necessary resources; and

4.2.1.3 The work does not begin until there is agreement between the laboratory and the client.

- 4.2.2 Records of the application review and client discussions are maintained in the laboratory. (See Section 13 Records.)
- 4.2.3 Application reviews include any work that is subcontracted by the laboratory. The client is informed of any deviations from the application; if the application is amended after the work starts, the same review process is followed for an amendment to the application
- 4.2.4 The laboratory cooperates with the client to ensure that the application is understood. The laboratory calls the client upon receipt of the application and reviews the application with the client. Prior to testing the laboratory and the client discuss any abnormalities.